

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

IN RE JUBLIA

Case No. 3:18-cv-13635 (BRM) (LHG)

**OPINION**

**MARTINOTTI, DISTRICT JUDGE**

Before this Court are the applications by Plaintiffs Bausch Health US, LLC, Bausch Health Ireland Limited, Bausch Health Americas, Inc., and Kaken Pharmaceutical Co., Ltd. (“Karen”) (collectively, “Plaintiffs”) and Defendants Aleor Dermaceuticals Ltd. (“Aleor”), Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively, “Aurobindo”), KVK-Tech, Inc. (“KVK”), Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”), and Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Cadila Healthcare Limited (collectively, “Zydus”) (together with Aleor, Aurobindo, KVP, and Lupin, “Defendants”) for claim construction to resolve disputes over two claim terms: “bottom portion” and “tip portion.” (ECF Nos. 190–91 & 204–05.)

This Court has examined the disputes over the construction of these claim terms and, for the reasons set forth in this Opinion, and for good cause shown, this Court defines the disputed claim term “bottom portion” to mean “the lateral surface that is bonded to the tubular body,” and “tip portion” to mean “the fan-shaped end of the columnar brush member.”

**I. BACKGROUND**

**A. Factual Background**

This case arises out of an action for infringement of Karen’s patent, U.S. Patent No. 10,478,601 (“the ’601 patent”), by Defendants’ filing of an Abbreviated New Drug Application

(“ANDA”) seeking U.S. Food and Drug Administration (“FDA”) approval to market a generic version of Plaintiffs’ product Jublia®—an efinaconazole topical solution, 10%. (ECF No. 191 at 5.)

On November 19, 2019, the United States Patent and Trademark Office (“PTO”) issued the ’601 patent, which describes a solution applicator “with which irritation on an affected part of a patient may be reduced even when a solution is used.” (ECF No. 191-2 at 3.) Onychomycosis is an infection of the nail unit caused by fungi. (ECF No. 191 at 6–7.) The parties dispute the proper construction of two claim terms “bottom portion” and “tip portion” used in the ’601 patent. The chart below sets forth the parties’ proposed constructions.

<b>Claim Language</b>	<b>Asserted Claims</b>	<b>Plaintiffs’ Proposed Construction</b>	<b>Defendants’ Proposed Construction</b>
“bottom portion”	’601 patent claim 8	Plain and ordinary meaning, i.e., “the lateral surface that is bonded to the tubular body”	“the lateral surface that is bonded to the lowest end of the tubular body of the bottomed tubular holder”
“tip portion”	’601 patent claim 8	Plain and ordinary meaning, i.e., “end portion of the columnar brush member”	“fan-shaped end of the columnar brush member”

### **B. Procedural History**

On September 6, 2018, Plaintiffs filed a Complaint asserting claims of infringement against Defendants. (ECF No. 1.) On March 5, 2019, Defendants filed an Answer to the Complaint along with counterclaims asserting the noninfringement and invalidity of the patents-in-suit. (ECF No. 20.)

On September 18, 2020, both Plaintiffs and Defendants filed their opening *Markman* briefs. (ECF Nos. 190 & 191.) On October 7, 2020, both Plaintiffs and Defendants filed their *Markman* reply briefs. (ECF Nos. 204 & 205.)<sup>1</sup>

## II. LEGAL STANDARD

Claims define the scope of the inventor's right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope and is a determination reserved exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) (*en banc*). Indeed, the court can only interpret claims and “can neither broaden nor narrow claims to give the patentee something different than what [it] has set forth” in the specification. *E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1998). A court's determination “of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996) (holding that “[t]he focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the term to mean”); *Phillips*, 415 F.3d at 1312–13. In construing the claims, the court may examine both intrinsic evidence (e.g.,

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<sup>1</sup> Plaintiffs and Defendants agreed a claim construction hearing is not necessary because the issues can be decided on the papers without argument. (ECF No. 206.)

the patent, its claims, the specification, and the prosecution history) and extrinsic evidence (e.g., expert reports and testimony). *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).

The analysis of claim language begins with determining the “ordinary and customary meaning of a claim term[, which] is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313. Further, the language should not be read solely in the context of the claim under review; instead, it should be analyzed “in the context of the entire patent” and with an understanding of how that language is used in the field from which the patent comes. *Id.* In conducting this review, a different interpretation is placed on a term located in an independent claim than on those located in dependent claims, and it is understood that each claim covers different subject matters. *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1331 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1315 (holding that “the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim”))).

In reviewing the language of a patent, “the court starts the decision-making process by reviewing the same resources as would [a person of ordinary skill in the art in question], viz., the patent specifications and the prosecution history.” *Phillips*, 415 F.3d at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). When “the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent,” understanding claim construction “involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. “In such circumstances, general purpose dictionaries may be helpful” to explain the terms used. *Id.*

Often times, however, the ordinary meaning of the claim language is not readily apparent, and in such circumstances, courts look to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). Those sources may include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* Furthermore, claims must be read in view of the claim specification, which is of seminal importance in providing framework for understanding the claim language. As the Federal Circuit in *Markman* explained:

The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. As we have often stated, a patentee is free to use his [or her] own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification. The written description part of the specification itself does not delimit the right to exclude. That is the function and the purpose of the claims.

*Markman*, 52 F.3d at 979–80.

This Court’s reliance on the specification is appropriate given the Patent and Trademark Office’s rules requiring “that application claims must ‘conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent bases in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.’” *Phillips*, 415 F.3d at 1316–17 (quoting 37 C.F.R. § 1.75(d)(1)). During this analysis, however, courts should not “import limitations from the specifications into the claims.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quoting *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005)).

The patent's prosecution history is also of "primary significance in understanding the claims." *Markman*, 52 F.3d at 980. "The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317. Further, the prosecution history is also relevant to determining whether the patentee disclaimed or disavowed the subject matter, thereby narrowing the scope of the claim terms. *Seachange Int'l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372–73 (Fed. Cir. 2005).<sup>2</sup>

In addition to intrinsic evidence, a court may also rely on extrinsic evidence in interpreting a claim. *Phillips*, 415 F.3d at 1317. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* (citations omitted). However, while extrinsic evidence "can shed useful light on the

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<sup>2</sup> "[I]n certain cases, 'the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor.'" *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) (quoting *Phillips*, 415 F.3d at 1316) (internal citations omitted). In such cases, the Federal Circuit interprets the claim more narrowly than it otherwise would in order to give effect to the patentee's intent to disavow a broader claim scope. *Ventana*, 473 F.3d at 1181 (citing *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319–20 (Fed. Cir. 2006); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342–44 (Fed. Cir. 2001)). However, pointing solely to "general statements by the [patentee] indicating that the invention is intended to improve upon prior art" will not demonstrate that the patentee intended to "disclaim every feature of every prior art device discussed in the 'BACKGROUND ART' section of the patent." *Ventana*, 473 F.3d at 1181; *see also Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal."). Moreover, the Federal Circuit has found it "particularly important not to limit claim scope based on statements made during prosecution '[a]bsent a clear disavowal or contrary definition.'" *Digital-Vending Servs. Int'l, LLC v. Univ. of Phx., Inc.*, 672 F.3d 1270, 1276 (Fed. Cir. 2012) (citing *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1286 (Fed. Cir. 2011) (quoting *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004))). The reason for such a stringent rule is "because the prosecution history represents an ongoing negotiation between the PTO and the applicant," and "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Digital Vending*, 672 F.3d at 1276 (quoting *Phillips*, 415 F.3d at 1317).

relevant art,” it is “less significant that the intrinsic record in determining the legally operative meaning of claim language.” *Id.* Extrinsic evidence should be “considered in the context of intrinsic evidence,” as there are flaws inherent in the exclusive reliance on extrinsic evidence, including, *inter alia*, biases, inadvertent alterations of meanings, and erroneous contextual translations. *Id.* at 1318–19. Furthermore, extrinsic evidence should not be relied upon where “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

### **III. DECISION**

This Court addresses the interpretation of two disputed claim terms “bottom portion” and “tip portion.”

#### **A. The Meaning of “Bottom Portion”**

Plaintiffs propose “bottom portion” be construed to have its plain and ordinary meaning, i.e., “the lateral surface that is bonded to the tubular body” (ECF No. 191 at 21), whereas Defendants propose “bottom portion” be construed to mean “the lateral surface that is bonded to the lowest end of the tubular body of the bottomed tubular holder” (ECF No. 190 at 12).

Plaintiffs contend the bottom portion does not have to be at the lowest end of the tubular body. (ECF No. 191 at 22.) First, no language in the claims or the specification suggests the bottom portion must be bonded to the lowest end. (*Id.* at 22, 24.) To the contrary, claim 8 states one purpose of the bottom portion is to provide a pore that controls the amount of solution moving from the solution container to the bottomed tubular holder. (ECF No. 205 at 6.) Fulfilling this purpose does not require the pore to be at the lowest end of the tubular body. (*Id.*) Second, the embodiments in Figures 18 and 22 of the specification contain a space between the lowest end of the tubular body and the bottom portion, thereby confirming the bottom portion is not limited to

the lowest end. (*Id.* at 8.) Third, Plaintiffs refer to certain dictionary definitions for “bottom” as the lowest point or surface inside something, which does not have to also be the lowest end of that something. (ECF No. 191 at 26.)

However, Defendants argue the bottom portion must be at the lowest end of the tubular body. (ECF No. 190 at 12.) First, the language of claim 8 states the solution must pass through the pore to enter into the bottomed tubular holder. (*Id.* at 14.) Therefore, the bottom portion, where the pore is located, must be located at the lowest end of the bottomed tubular holder. (*Id.*) Otherwise, the solution could enter the bottom tubular holder without first passing through the pore. (*Id.*) Moreover, Plaintiffs’ construction allows the bottom portion to be bonded anywhere along the tubular body, including at the top. (*Id.* at 16.) If the bottom portion is bonded at the top of the tubular body, the solution would exit the bottomed tubular holder through the pore, which contradicts the language of claim 8. (*Id.*) Second, the specification repeatedly uses “bottom” consistent with its plain meaning offered by Defendants. (*Id.*) Each time the word “bottom” is used, it spatially refers to the “lowest” part of the component it is discussing, such as the bottom portion of the solution container, the bottom face of the annular flange and the solution container, and a schematic bottom view illustrating a lid member viewed from below. (*Id.* at 16–18.) Third, as for the embodiments in Figure 18, Defendants maintain the space between the absolute bottom of the tubular body and the bottom portion is nominal. (ECF No. 204 at 13.) It is simply the result of the design of the bottomed tubular holder, which requires the bottom portion be bonded to the tubular body. (*Id.*) Fourth, Defendants claim the extrinsic evidence supports Defendants’ proposed construction, as each of the dictionary definitions mentioned by Plaintiffs makes clear the word “bottom” has a spatial meaning that connotes the lowest part. (*Id.* at 17–18.)

Plaintiffs object to Defendants’ construction of the language of claim 8, contending



Defendants view the claim term in isolation, divorced from the context of the claim as a whole. (ECF No. 205 at 7.) Plaintiffs argue the bottom portion provides a pore through which the solution reaches the functional space, rather than the inside, of the bottomed tubular holder. (*Id.*) The functional space is the space above the bottom portion, where the columnar brush member is inserted. (*Id.*) Plaintiffs claim only such a construction is consistent with the language of claim 8, which expressly recites the solution enters the bottomed tubular holder via the pore “to reach an end face of the columnar brush member.” (*Id.*) Moreover, when the specification discusses the solution entering the bottomed tubular holder, it is also in the context of entering the functional space. (*Id.* at 9–10.) Therefore, contrary to Defendants’ assertion, the solution may touch the inside of the tubular body before it enters the functional space through the pore of the bottom portion to reach the end face of the brush. (*Id.* at 7.)

The Court finds the bottom portion does not have to be at the lowest end of the tubular body of the bottomed tubular holder.

**1. The Bottom Portion Defines the Lowest End of the “Inside” of the Bottomed Tubular Holder**

A critical question here is how to define the “inside” of the bottomed tubular holder: whether the lowest end of the “inside” is the bottom portion or the lowest end of the tubular body. Despite the absence of an explicit definitional statement in the patent, the specification suggests the answer is the bottom portion, through a series of consistent references to the scope of the “inside.” See *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1328 (Fed. Cir. 2002) (holding a patentee may define a claim term by implication, through the term’s consistent use throughout the specification). First, the solution in the solution container must come “inside” the bottomed tubular holder via the pore. (ECF No. 191-2 at 12:58–59.) This suggests only the space above the bottom portion, where the pore is located, is called the “inside.” Second, the bottom portion is

between the solution container and the columnar brush member. (*Id.* at 3:15–16.) Since the columnar brush member is above the bottom portion, the space on the opposite side (i.e., beneath the bottom portion) should belong to the solution container, rather than the “inside” of the bottomed tubular holder. Third, the pore controls the amount of a solution moving from the solution container to the bottomed tubular holder. (*Id.* at 12:63–66.) The pore can only control the flow of solution across the bottom portion’s lateral surface, which therefore sets the boundary between the solution container and the bottomed tubular holder. That means the space above the bottom portion belongs to the bottomed tubular holder, and the space below belongs to the solution container.

As a result, Defendants’ argument—if the bottom portion is not at the lowest end of the tubular body, then the solution could enter the bottom tubular holder without first passing through the pore—fails, because the solution enters the bottom tubular holder only after passing through the pore. Therefore, the bottom portion does not have to be at the lowest end of the tubular body.

However, such a construction does not mean, as Defendants assert, the bottom portion can be bonded anywhere along the tubular body. Inside the bottomed tubular holder is a supporting member that supports an inserted columnar brush member. (*Id.* at 3:25–29.) Since the bottom portion defines the lowest end of the inside of the bottomed tubular holder, the bottom portion cannot be bonded above the supporting member.

## **2. The Embodiment in Figure 18 Shows the Bottom Portion Need Not Be at the Lowest End of the Tubular Body**

“A [patent claim] construction that excludes a preferred embodiment is rarely, if ever correct and would require highly persuasive evidentiary support.” *EPOS Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1347 (Fed. Cir. 2014) (citing *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003)). “[The Federal Circuit has]

interpreted claims to exclude embodiments of the patented invention where those embodiments are clearly disclaimed in the specification.” *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008). Here, any highly persuasive evidentiary support to exclude the embodiment in Figure 18 is absent. Therefore, a proper construction of “bottom portion” should not ignore the teachings from Figure 18, where the bottom portion is not at the lowest end of the tubular body. (ECF No. 191-2 at fig. 18.)

Defendants argue the space between the lowest end of the tubular body and the bottom portion is nominal. (ECF No. 204 at 13.) Defendants state some nominal space will inevitably be produced after the bottom portion and the tubular body are bonded together, and therefore cannot change the fact that the bottom portion in Figure 18 is located at the tubular body’s lowest end. (*Id.* at 14.) The Court disagrees.

Defendants’ statement could be interpreted in two ways. First, it may mean the “nominal” space results from an imperfection in the applicator’s manufacturing process. If so, Figure 18 should not contain such a space. A manufacturing error like the “nominal” space may exist in an actual applicator, but not in its product design. After all, a manufacturing error is something that is “not in the form intended by, or fails to perform in accordance with” the product design. 16 C.F.R. § 1115.4. A preferred embodiment represents “the actual product design that the inventor intends to use.” Morgan D. Rosenberg, *Essentials of Patent Claim Drafting* (2021 Edition) § 1.03 (Matthew Bender). As for the preferred embodiment in Figure 18, Defendants offer no reason why it would incorporate a manufacturing error that deviates from the bottomed tubular holder’s design. Therefore, this “nominal” space is unlikely a manufacturing error. Alternatively, Defendants’ statement may mean the “nominal” space is a component of the bottomed tubular holder’s design, but the space is negligible. However, Defendants only conclusively state the space is “nominal,”

without presenting any relevant evidence. With proper numerical data or standards, a party may claim a physical element associated with a patent is nominal or negligible. *See In re Brandt*, 886 F.3d 1171, 1177 (Fed. Cir. 2018) (finding the claimed density range of “less than 6 pounds per cubic feet” and the prior art range of “between 6lbs/ft<sup>3</sup> and 25lbs/ft<sup>3</sup>” are so mathematically close that the range difference is “virtually negligible”); *Noven Pharms., Inc. v. Mylan Techs. Inc.*, No. 17-1777, 2018 U.S. Dist. LEXIS 144722, at \*5 n.4 (D. Del. Aug. 20, 2018) (calling a flux rate of 0.01 mg/cm<sup>2</sup>/day or less “nominal”); *Jiffy Enters., Inc. v. Sears, Roebuck & Co.*, 306 F.2d 240, 243 (3d Cir. 1962) (confirming, beyond any reasonable doubt, the differences in weight, mobility of the hook, or thickness between two hangers are not readily perceptible to the senses and therefore “negligible”); *Glaxo Wellcome, Inc. v. Genentech, Inc.*, 136 F. Supp. 2d 316, 336 (D. Del. 2001) (calling a degradation rate at less than 1% of a designated peak value “negligible”). Defendants provide none of these reasonings. Therefore, the Court does not find the space is so negligible that the bottom portion in Figure 18 can be characterized as at the lowest end of the tubular body.

### **3. The Court Need Not Consider the Meaning of “Bottom” in Other Components of the Invention**

In addition to the bottom portion of the bottomed tubular holder, the word “bottom” is used to describe other components of the applicator, such as the bottom portion of the solution container, and the bottom face of the annular flange and the solution container. (ECF No. 190 at 16–18.) But even if the word “bottom” spatially refers to the lowest part of these other components, it does not prove the word “bottom” in the disputed term “bottom portion” must have the same meaning.

In claim construction, the same word or term used in different phrases will not necessarily be interpreted to have the same meaning, because these different phrases may represent different contexts for the same word or term, thereby attaching different connotations to it. *See Epcon Gas*

*Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1031 (Fed. Cir. 2002) (finding the word “substantially” used in two contexts had different meanings: the phrase “substantially constant” denoted language of approximation, while the phrase “substantially below” signified language of magnitude); *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1258 (Fed. Cir. 2007) (construing the term “coupled to” differently in “input terminals coupled to receive first and second input variables” versus “second stage input terminal coupled to the first stage output terminal”); *Senior Techs., Inc. v. R.F. Techs., Inc.*, 2001 U.S. App. LEXIS 4179, at \*23 (Fed. Cir. March 12, 2001) (finding that the word “enable” implied different ways of enabling the receiving circuit, where the phrase in claim 6, “to enable the receiving circuit,” existed in a bare form, and the two phrases in claim 1, “to enable the sensing module” and “to enable the receiving circuit in the sensing module,” were qualified by additional limitations). After all, “[t]he meaning of a phrase is often greater than the sum of the individual words.” *ADE Corp. v. KLA-Tencor Corp.*, 252 F. Supp. 2d 40, 58 (D. Del. 2003).

Here, the word “bottom” is used in different contexts when it describes different components of the applicator. Each component has its own distinct limitations, which attach distinct meanings to the word “bottom.” The Court should not simply import the meaning of “bottom” used in describing other components into the disputed term “bottom portion.”

Accordingly, the Court defines “bottom portion” as “the lateral surface that is bonded to the tubular body.” The bottom portion is not necessarily at the lowest end of the tubular body. Since intrinsic evidence has clarified the meaning of “bottom portion,” the Court need not examine extrinsic evidence such as dictionary definitions.

## **B. The Meaning of “Tip Portion”**

Plaintiffs propose “tip portion” be construed to have its plain and ordinary meaning, i.e.,

“end portion of the columnar brush member” (ECF No. 191 at 27), whereas Defendants propose “tip portion” be construed to mean the “fan-shaped end of the columnar brush member” (ECF No. 190 at 21).

### **1. The Tip Portion Is Fan-Shaped**

Plaintiffs maintain the tip portion should not be limited to a fan shape. First, the claim language indicates the tip portion can be any shape, so long as it sits at the end portion of the brush. (ECF No. 205 at 14.) Claim 8 recites a tip portion without specifying its shape, while claim 9, which depends on claim 8, further narrows the tip portion to those that are fan-shaped. (*Id.*) Claims 1 and 10 also refer to the tip portion as fan-shaped. (*Id.* at 15.) This shows, when the patentee wants to claim a tip portion of any shape (as in claim 8) or more narrowly only a fan-shaped tip portion (as in claims 1, 9, and 10), the patentee knows how to do it. (*Id.*) Under the doctrine of claim differentiation, the tip portion in independent claim 8 is not limited to a fan shape when its dependent claim 9 adds a fan shape limitation to the tip portion. (*Id.* at 14–15.) Second, when the specification recites the tip portion in the context of claim 8, i.e., the solution flowing through the columnar brush member, a particular tip shape is not required. (*Id.* at 16–17.) Even though the specification, in other instances, recites the term “tip portion” with a fan shape limitation, it does not indicate the tip portion in all the contexts of the invention should be fan-shaped. (*Id.*) Third, achieving the stated objective of the invention, i.e., providing an applicator capable of reducing irritation on an affected part of a patient, does not require a particular shape of the tip portion. (*Id.* at 18.) Rather, the specification attributes the reduced irritation to the softness of the tip portion. (*Id.*) Fourth, the problems in the prior art, as described in the specification and which the ’601 patent purports to overcome, are neither caused nor solved by the shape of the tip portion. (*Id.* at 19.)

However, Defendants argue the fan shape is an essential feature of the tip portion. (ECF No. 190 at 22.) First, the specification, in multiple instances, describes “the present invention” as an applicator where the tip portion of the columnar brush member has a fan shape, and specifically refers to the “fan-shaped columnar brush member tip portion.” (*Id.* at 22, 24.) In particular, both of the two examples in the specification discuss a fan-shaped tip portion. (*Id.* at 24.) Second, in both the specification and the prosecution history of the ’601 patent, the patentee distinguishes the claimed invention from the prior art based on a fan-shaped tip portion. (*Id.* at 27–28.)

Plaintiffs object to Defendants’ understanding of the prosecution history relating to the fan shape. (ECF No. 205 at 21.) The patentee’s statements distinguishing prior art on the basis of the fan-shaped tip portion were made in the context of arguing the patentability of claims that expressly recite the fan shape limitation, and do not apply to claim 8 that does not expressly recite that very limitation. (*Id.* at 21–22.) Plaintiffs argue the fan-shape limitation alone did not overcome any of the prior art and was not critical to allowance of the claims. (*Id.* at 25.)

The Court finds the tip portion must be fan-shaped.

**a. The Claim Language Indicates the Tip Portion Is Fan-Shaped**

“A claim must be read in accordance with the precepts of English grammar.” *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983). “[T]he definite article ‘the’ particularizes the subject which it precedes.” *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1306 (Fed. Cir. 2005) (internal citations omitted). “It is a word of limitation as opposed to the indefinite or generalizing force of ‘a’ or ‘an.’” *Id.* In a patent claim, “the introduction of a new element is accomplished through the use of an indefinite article, not through the use of a definite article.” *Tuna Processors, Inc. v. Haw. Int’l Seafood, Inc.*, 327 F. App’x 204, 210 (Fed. Cir. 2009). “The definitive article ‘the’ is used to refer to an element which has been established earlier in a claim.” *Id.* If that element is not

established earlier in the same claim, the definitive article may refer to an element established in an earlier claim. *See Vidor Mach. Inc. v. United Fixtures Co.*, 570 F. Supp. 2d 693, 699 (M.D. Pa. 2008) (The patentee concedes “the elongate member” in dependent claims 15 and 16 refers to “an elongate flexible drive member” identified in independent claim 13); *Advanced Tech. Incubator, Inc. v. Sharp Corp.*, 2009 U.S. Dist. LEXIS 109173, at \*34 (E.D. Tex. June 26, 2009) (finding the phrase “the continuous layer of transparent conductive material” in independent claim 22 refers to an element recited in dependent claim 9).

Here, the term “tip portion” in claim 8 is preceded by the definite article “the,” not the indefinite article “a.” (ECF No. 191-2 at 18:1.) The term does not appear earlier in claim 8. The only prior recitations of the “tip portion” of the columnar brush member are in claims 1 and 2, where the tip portion is fan-shaped. (*Id.* at 16:33–34, 17:11.) Therefore, the term “tip portion” in claim 8 could only refer to the fan-shaped tip portion in claims 1 and 2.

Though not determinative to the construction of claim 8, the Court notices the term “tip portion” in claim 9 is preceded by the indefinite article “a,” which suggests it does not refer to “the tip portion” or “a tip portion” in a preceding claim. As a result, claim differentiation has no application between claims 8 and 9, because the term “tip portion” in each claim covers a distinct subject matter. *See InterDigital Commc’ns., LLC v. USITC*, 690 F.3d 1318, 1325 (Fed. Cir. 2012) (rejecting the argument that claim differentiation did not apply between two claims because the disputed term in the two claims covered different subject matters, and finding the term covered the same subject matter in the two claims). If “a tip portion” in claim 8 is actually meant to refer to “a tip portion” in claim 1 or “the tip portion” in claim 8, it could be the basis for an indefiniteness rejection under 35 U.S.C. § 112. *See Alcon Research, Ltd. v. Watson Labs., Inc.*, 2017 U.S. Dist. LEXIS 21400, at \*21 (D. Del. Feb. 15, 2017).



**b. The Prosecution History Imposes a Fan Shape Limitation**

“[A] patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution.” *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006). A patentee could do so by clearly characterizing the invention in a way (i.e., arguing a claim possesses a feature that the prior art does not possess) to try to overcome a prior art rejection. *Id.* (internal citations omitted); *see also Seachange Int’l*, 413 F.3d at 1372–73; *Comput. Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008). “[B]y distinguishing the claimed invention over the prior art,” a patentee “is indicating what the claims do not cover” and “by implication surrendering such protection.” *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir. 2009) (citing *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997)).

“A disavowal of scope as to the general nature of an invention limits all claims where the statements made in prosecution history are not associated with particular claim language.” *iLight Techs., Inc. v. Fallon Luminous Prods. Corp.*, 380 F. App’x 978, 980 (Fed. Cir. 2010) (citing *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1315–16 (Fed. Cir. 2007)). “Only disclaimers that distinguish the prior art by focusing on a particular claim limitation are not directed to the invention as a whole.” *Id.* (citing *Saunders Grp.*, , 492 F.3d at 1333). “In determining whether a clear and unambiguous disclaimer attaches to particular claim language, it is important to consider the statements made by the applicant both in the context of the entire prosecution history and the then-pending claims.” *MIT v. Shire Pharms., Inc.*, 839 F.3d 1111, 1120 (Fed. Cir. 2016).

During the prosecution of the ’601 patent, the patentee on three occasions argued the applicator possessed a fan-shaped tip portion that the prior art did not possess. The first occasion involved the originally filed claim 1, which recited an applicator with “a tip portion of the columnar

brush member outside the solution container [that] has a fan shape.” (ECF No. 190-3 at 3.) The examiner rejected the claim for obviousness over U.S. Patent No. 6,073,634 (“Gueret”) because Gueret taught all the limitations of the claimed applicator, including a fan-shaped tip portion of the columnar brush member. (*Id.* at 10–11.) In response, the patentee countered the tip portion in Gueret was only “a convex shape,” rather than “a fan shape extending in a perpendicular lateral direction against a pillar axial lengthwise direction.” (*Id.* at 22.) The examiner maintained the rejection, arguing Gueret did teach the shape of a fan. (*Id.* at 39.) The second occasion involved the amended claim 1 submitted by the patentee. The patentee made amendments (unrelated to the fan shape) to claim 1 (*Id.* at 69–70), after an obviousness rejection based on U.S. Publication No. 2009/0279937 (“Peck”) which the examiner stated had a fan-shaped tip portion (*Id.* at 58). The patentee argued the tip portion in Peck did not meet the recitation of a fan shape with the direction and thickness features<sup>3</sup> identified in then claim 1. (*Id.* at 73–74.) But the examiner again rejected and maintained Peck possessed a fan-shaped tip portion with the above direction and thickness features. (*Id.* at 83.) The third occasion came after the patentee canceled all then pending claims and added new claims. (*Id.* at 131.) All the newly added claims include a fan shape limitation for the tip portion, except for claim 19 which was ultimately issued as claim 8 in the ’601 patent. (*Id.* at 131–37.) In explaining the newly added claims are not obvious over Peck, the patentee contended the columnar brush member in Peck was “tapered or pseudo-tapered,” and presented a

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<sup>3</sup> “a fan shape extending in a perpendicular lateral direction against a pillar axial lengthwise direction, and a thickness of the fan-shaped tip portion of the columnar brush member decreases in a perpendicular lengthwise direction against the pillar axial lengthwise direction toward the tip portion of the columnar brush member” (ECF No. 190-3 at 69.)

new ground<sup>4</sup> to argue the tip portion in Peck did not have a fan shape with the direction and thickness features<sup>5</sup> as identified in then claim 12. (*Id.* at 142–43.)

Each of the above disavowals counts as a statement by the patentee on the shape of the “tip portion” of the columnar brush member. The Court need not determine whether these disavowals are directed to the invention as a whole or a particular claim term. If these disavowals are directed to the entire invention, then they will apply to all the patent claims, including claim 8. If not, they will still apply to claim 8 anyway. After all, claim 8 contains the very claim term “tip portion” that these disavowals focus on. Therefore, the prosecution history limits the tip portion in claim 8 to a fan shape.

**c. The Specification Restricts the Tip Portion to a Fan Shape**

The patent claims must be construed in view of the specification, but not everything in the specification will be read into the claims. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002). Nevertheless, the specification may limit the scope of the claims in two ways: lexicography and disavowal. *Hill-Rom Servs. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). “The standards for finding lexicography and disavowal are exacting.” *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). “[A]n inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention ‘with reasonable clarity, deliberateness, and precision.’” *Teleflex*, 299 F.3d at 1325 (citing *In re Paulsen*,

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<sup>4</sup> Peck only provides a 2-dimensional view for its tip portion (ECF No. 190-3 at 143), and therefore cannot describe certain 3-dimensional features of the tip portion as stated in the newly added claims.

<sup>5</sup> “a fan shape extending in a perpendicular lateral direction against a pillar axial lengthwise direction, and a thickness of the fan-shaped tip portion of the columnar brush member decreases in a perpendicular lengthwise direction against the pillar axial lengthwise direction toward the tip portion of the columnar brush member” (ECF No. 190-3 at 131.)

30 F.3d 1475, 1480, 31 U.S.P.Q.2D (BNA) 1671, 1674 (Fed. Cir. 1994)). Alternatively, the patentee may include “in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.” *Id.* (citing *SciMed Life Sys.*, 242 F.3d at 1344).

An explicit statement of definition or disavowal is not necessary. *Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1364 (Fed. Cir. 2016). “[T]he specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents.” *Id.* (internal citations omitted). For example, “an inventor may disavow claims lacking a particular feature when the specification describes ‘the present invention’ as having that feature.” *Poly-America, L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016) (internal citations omitted). Also, “[w]hen a patentee ‘describes the features of “the present invention” as a whole,’ he alerts the reader that ‘this description limits the scope of the invention.’” *Pacing Techs., LLC v. Garmin Int’l, Inc.*, 778 F.3d 1021, 1025 (Fed. Cir. 2015) (internal citations omitted). “While clear language characterizing ‘the present invention’ may limit the ordinary meaning of claim terms, such language must be read in context of the entire specification and the prosecution history.” *Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1094 (Fed. Cir. 2003) (refusing to limit a disputed term when most references to the term in the specification do not contain the purported limitation as recited in a single paragraph describing “the present invention”).

The Court finds the specification of the ’601 patent contains clear statements of disavowal which indicate the tip portion is fan-shaped. First, the first paragraph of the “summary of the invention” explains:

the *present invention* provides an applicator, comprising a solution container having an opening and a columnar brush member formed by bundling synthetic fibers in a columnar shape, wherein the columnar brush member disposed at the opening of the solution container, a tip portion of the columnar brush member outside the solution container *has a fan shape* extending in a perpendicular

lateral direction against a pillar axial lengthwise direction, and a thickness of the fan-shaped tip portion of the columnar brush member decreases in a perpendicular lengthwise direction against the pillar axial lengthwise direction toward the tip portion of the columnar brush member.

(ECF 191-2 at 2:36–49.) “When a patent thus describes the features of the ‘present invention’ as a whole, this description limits the scope of the invention.” *Regents of the Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 936 (Fed. Cir. 2013) (finding a similar first paragraph<sup>6</sup> of the summary of the invention limits the scope of the invention) (internal citations and quotations omitted). Second, “advantageous effect of the invention” states:

[t]he tip portion of the columnar brush member used in the *present invention* outside the solution container *has a fan shape*, and a thickness of the fan-shaped tip portion of the columnar brush member decreases toward the tip of the columnar brush member.

(ECF 191-2 at 3:45–49.) The above two statements are not isolated, as the remainder of the specification is replete with references of a fan-shaped tip portion. (*See, e.g., id.* at 2:29–30, 3:50–53, 7:63–65, 8:15–16, 9:12.) The specification never describes a tip portion that adopts a different shape. Therefore, the specification, read as a whole, imposes a fan-shape limitation on the disputed term “tip portion,” including that in claim 8.

In sum, the ’601 patent’s claim language, prosecution history, and specification all indicate the tip portion of the columnar brush member must be fan-shaped. The Court need not refer to the doctrine of claim differentiation, which is “not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history.” *Regents of the*

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<sup>6</sup> “The present invention provides a simple, reliable device for effectively occluding a septal defect. The instant closure device includes first and second occluding disks which are attached to one another. . . . A central portion of the membrane of each disk is affixed to a corresponding portion of the membrane of the other disk, thereby attaching the two disks directly to one another at their centers. The affixed central portion of the two membranes define[] a central ‘conjoint disk’ of the device . . . .” *Regents of the Univ. of Minn.*, 717 F.3d at 936.

*Univ. of Cal. v. DakoCytomation Cal., Inc.*, 517 F.3d 1364, 1375 (Fed. Cir. 2008) (citing *Seachange Int'l*, 413 F.3d at 1369).

## **2. The Tip Portion Is the Fan-Shaped End Opposite to the End Face**

Both parties agree the tip portion is located at an end of the columnar brush member. (ECF No. 190 at 21.) However, Defendants contend “tip portion” should be more narrowly construed than a generic “end portion.” (ECF No. 204 at 22.) Defendants argue “tip portion” can only be the fan-shaped end portion that is opposite to the end face. (ECF No. 190 at 22.) The Court agrees.

The columnar brush member has two ends, which are separately termed as “tip portion” and “end face” in claim 8. (ECF No. 191-2 at 17:67–18:1.) The two ends are different functionally. The plain language of claim 8 indicates a solution that “enters the bottomed tubular holder” will first reach “an end face of the columnar brush member” and then “to the tip portion opposite to the end face of the columnar brush member by capillarity.” (*Id.* at 17:60–18:2.) Besides, the two ends are different structurally. Only the tip portion is fan-shaped; nowhere in the ’601 patent or its prosecution history suggests the end face may be fan-shaped. Therefore, the tip portion must be the fan-shaped end of the columnar brush member that is opposite to the end face.

Accordingly, the Court defines “bottom portion” as “the lateral surface that is bonded to the tubular body,” and “tip portion” as “the fan-shaped end of the columnar brush member.”

## **IV. CONCLUSION**

For the reasons set forth above, this Court defines the disputed claim terms “bottom portion” to mean “the lateral surface that is bonded to the tubular body,” and “tip portion” to mean “the fan-shaped end of the columnar brush member.” An appropriate order follows.

**Date: January 11, 2020**

**/s/ Brian R. Martinotti**  
**HON. BRIAN R. MARTINOTTI**  
**UNITED STATES DISTRICT JUDGE**